

Summary of Safety and Effectiveness

Excel OneStep Urine hCG Pregnancy DipStick Test

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Excel OneStep Urine hCG Pregnancy DipStick Test is Excel Scientific, Inc.'s name for professional use of solid phase migratory chromatography immunoassay *in vitro* diagnostic test kit for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine. Excel OneStep Urine hCG Pregnancy DipStick Test is based on comparative data with Syntrol Quikpac EIA, an assay for human Chorionic Gonadotropin currently being marketed.

The Principle of Excel OneStep Urine hCG Pregnancy DipStick Test is as follows:

- Both the Excel OneStep Urine hCG Pregnancy DipStick and the QuikStrip (or E.Z. Strip) Pregnancy Home tests are a sandwich solid phase dye-conjugated non-enzyme immunoassay. When the Excel OneStep Urine hCG Pregnancy DipStick is placed in a urine test cup containing the urine specimen, the urine will migrate by capillary action. The gold sol-antibody conjugate in the gold sol pad of the Excel OneStep Urine hCG Pregnancy DipStick binds to the hCG molecules in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody immobilized in the positive reaction zone in the white membrane area and produces a rose-pink color band when the hCG concentration is at or greater than 25 mIU/mL. In the absence of detectable levels of hCG, there is no rose-pink band in the positive reaction zone. The reaction mixture continues to flow through the absorbent device, pass the positive reaction zone, producing a rose-pink color band in the control zone of the white membrane area, demonstrating that the reagents and the device are functioning correctly.
- There is no difference in the testing procedure between the Excel OneStep Urine hCG Pregnancy DipStick Test and the Syntrol's QuikStrip (or E.Z. Strip) Pregnancy Home test as shown below :

	QuikStrip (or E.Z. Strip) Pregnancy Home test	Excel OneStep Urine hCG Pregnancy DipStick Test
Specimen Volume	6 drops	6 drops of urine
Incubation	5 minutes	5 minutes
Reagent	No	No
Step	one step	one step
Cutoff	25 mIU/mL	25 mIU/mL
Urine Cup	Yes	Yes

- The differences between the Excel OneStep Urine hCG Pregnancy DipStick Test and the Syntrol Quikpac EIA Pregnancy Test are as follows :

	Syntrol Quikpac EIA Pregnancy Test	Excel OneStep Urine hCG Pregnancy DipStick Test
Specimen Volume	3 drops of urine	6 drops of urine
Incubation	3 minutes with antibody and 3 minutes with substrate	5 minutes
Reagent	2 bottles	No
Step	3 steps	one step
Cutoff	25 mIU/mL	25 mIU/mL

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4. For questions concerning the safety and effectiveness of the Excel OneStep Urine hCG Pregnancy DipStick, please contact:

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